FBI Laboratory
Practices for Preventive Action

1 Purpose

The purpose of preventive action is to bring about continuous improvement through proactive measures, provide guidelines to identify potential nonconformities, and reduce the likelihood of nonconformities occurring. These practices also satisfy the requirements of the FBI Laboratory Quality Assurance Manual and the applicable accrediting body(ies).

2 Scope

These practices apply to FBI Laboratory personnel who are involved in the preventive action process.

3 Practices

3.1 Preventive Action

A preventive action is an action to eliminate the cause of a potential nonconformity or other undesirable potential situation. Preventive actions are initiated to identify opportunities for improvement and to reduce the likelihood of a nonconformity occurring. Any FBI Laboratory personnel may identify a potential situation or condition where a preventive action would be helpful.

3.1.1 Notification of Potential Situations or Conditions

If a situation or condition exists that may be improved, the person identifying the opportunity will notify their Unit Chief. Additionally, for technical matters, personnel will notify the appropriate Technical Leader. If the Unit Chief and/or Technical Leader determine a preventive action is appropriate they will ensure any other impacted Unit Chief(s) and the Quality Manager are notified in writing.

3.2 Initiating the *Preventive Action Request*

A *Preventive Action Request* (7-261) (Appendix A) is used to record and track preventive actions. This form identifies the potential situation or condition, the person responsible for managing the preventive action, the action step(s), and the expected date of completion of the action step(s). The *Preventive Action Request* will be initiated using the Forensic Analysis Support Unit (FASU) Corrective Action Request (CAR) database. Refer to the FASU Procedures for Entering Data in the Quality Assurance CAR Database to complete the steps listed below. The Unit Chief or Technical Leader will ensure the *Preventive Action Request* is

initiated. If a preventive action is identified through an internal audit or assessment, the Quality Manager or a Quality Assurance (QA) Specialist will initiate the *Preventive Action Request*.

3.2.1 Action Steps

Depending on the nature of the potential situation or condition, action steps should target the ways to improve the potential situation or condition and/or reduce the likelihood of a nonconformity occurring.

3.2.2 Accepting Preventive Action Steps

A QA Specialist will evaluate the proposed preventive action to determine its adequacy, acceptability of the planned action step(s), and the stated time frame. If the request is determined to be less than adequate, the person responsible for managing the preventive action will be required to amend the request. If the QA Specialist determines a *Preventive Action Request* is not appropriate, it may be changed to a *Corrective Action Request* (7-254) in accordance with the Laboratory Operations Manual (LOM) – Practices for Addressing a Nonconformity. If accepted, the Quality Manager will sign and date the bottom of the appropriate form in the space labeled "Reviewed and Accepted By" and forward a copy to the person responsible for managing the preventive action.

3.2.3 Completed Preventive Action Steps

The assigned QA Specialist will liaise with the person responsible for managing the preventive action to determine if the action step(s) is complete. If the action step(s) has been completed, the assigned QA Specialist will review objective evidence in support of its completion. The assigned QA Specialist will sign and date the bottom of the form in the space labeled "Actions Completed."

3.2.4 Closing Out a *Preventive Action Request*

The Quality Manager will sign and date the bottom of the *Preventive Action Request* in the space labeled "Closed Out" indicating approval for close out of the preventive action. The original *Preventive Action Request* will be retained in the FASU. A copy of the *Preventive Action Request* will be forwarded to the appropriate QA representative(s).

3.3 Tracking Progress on *Preventive Action Requests*

QA Specialists will track the progress of *Preventive Action Requests.*

4 Records

The following records will be generated and/or retained through one accreditation cycle as a result of these practices:

- Original *Preventive Action Requests* and associated records will be maintained in FASU.
- Other associated records will be maintained by the units.

5 References

FBI Laboratory Quality Assurance Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

FBI Laboratory Operations Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2017.

ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125), ANAB, Milwaukee, WI, April 29, 2019.

Rev. #	Issue Date	History
7	06/03/19	Updated list of references in section 5.
8	12/21/20	Grammatical and editing changes made throughout for clarity 5 – Added: LOM

Redacted - Signatures on File

Approval

Laboratory Director Date: 12/18/2020

Quality Manager Date: 12/18/2020

Appendix A: *FBI Laboratory Preventive Action Request* (7-261)

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